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NIXON & VANDERHYE, PC
901 NORTH GLEBE ROAD, 11TH FLOOR
ARLINGTON, VA 22203

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FRONDA, CHRISTIAN L	
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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 09/403,625
Filing Date: February 07, 2000
Appellant(s): DEBYSER ET AL.

B.J. Sadoff
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 04/08/2005.

(1) Real Party in Interest

A statement identifying the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

A statement identifying the related appeals and interferences which will directly affect or be directly affected by or have a bearing on the decision in the pending appeal is contained in the brief.

(3) Status of Claims

The statement of the status of the claims contained in the brief is correct.

(4) Status of Amendments After Final

No amendment after final has been filed.

(5) Summary of Invention

The summary of invention contained in the brief is correct.

(6) Issues

The appellant's statement of the issues in the brief is correct.

(7) Grouping of Claims

The rejection of claims 48-50, 52-56, and 65-68 stand or fall together because appellant's brief does not include a statement that this grouping of claims does not stand or fall together and reasons in support thereof. See 37 CFR 1.192(c)(7).

(8) Claims Appealed

The copy of the appealed claims contained in the Appendix to the brief is correct.

(9) Prior Art of Record

Proteins : Structures and Molecular Properties, 2nd ed.(1993), Thomas E. Creighton (see p. 4, Table 1.1)

(10) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claims 48-50, 52-56, and 65-68 are rejected under 35 U.S.C. § 112, 1st Paragraph. This rejection is set forth in a prior Office Action, mailed on 11/18/2004.

(11) Response to Argument

Appellants summarize the claimed invention on pages 7-17 of the Brief which is directed toward isolated protein or glycoprotein inhibitors of xylanase found in plants (and in particular cereals). On pages 14-16, the Brief states several physical and chemical properties of the claimed invention, where structural features of the claimed invention include an N-terminal amino acid sequence that is 70% homologous to SEQ ID NO: 1 (see p. 15, lines 7-10) and the claimed product resolves as two separate bands by SDS-PAGE analysis comprising an amino acid sequence of SEQ ID NO: 1 and SEQ ID NO: 2 (see p. 16, lines 7-12).

Beginning on page 17, line 14, Appellants argue that the Examiner's assertion that the specification only describes xylanase inhibitors containing SEQ ID NOs: 1and 2 is incorrect since the Examiner allegedly focuses only on exemplified embodiment of the wheat xylanase and fails to acknowledge the barley and rye inhibitors of the specification's examples (p. 20, line 18 to p. 21, line 24 of the specification) and the broader description of the genus of inhibitors of the specification. Appellants further

describe that claimed inhibitors is typically water-soluble, and the N-terminal sequence of the 40-43 kDa protein or glycoprotein is typically SEQ ID NO.1: Lys-Gly-Leu-Pro-Val-Leu-Ala-Pro-Val-Thr-Lys-Xaa-Thr-Ala, where Xaa is preferably Asp (see Brief on p. 18, lines 8-27). Appellants argue on page 19, lines 4-10, that the alternative recitations of factors (5)(i) or (9)(i) of Table of the Brief (see p. 12) is adequate to describe the N-terminal sequence of the claimed invention.

Appellants state beginning on page 20, line 9 of the Brief that a barely xylanase inhibitor disclosed in WO 01/98474 (US national phase of WO 01/98474 assigned as U.S. Serial No. 10/311,886) is an example of the claimed invention of inhibitors of xylanase. Appellants state that this barley inhibitor of xylanase (designated HvXI) has an N-terminal sequence of 20 amino acid residues that is 78.6% homologous to the 14 amino acid residues of SEQ ID NO: 1 of the claimed invention. Appellants conclude that this barley xylanase inhibitor HvXI is a species of the claimed invention. On page 21, lines 3-17, appellants argue that identification of the barley xylanase inhibitor disclosed in the specification and subsequent elucidation of its amino acid sequence serves as evidence that a further species of the presently claimed genus or subgenus exists.

Beginning on page 22, line 14 of the Brief, appellants presents the Patent Office's current understanding regarding the written description requirement of 35 U.S.C. § 112, 1st Paragraph. Appellants note that the *Eli Lilly* court confirmed that one of ordinary skill in the art can usually distinguished generic formula from others and can identify many of the species that the claims encompass, and the *Eli Lilly* court

concluded that "such a formula is normally adequate written description". Appellants argue that in view of the Patent Office's current understanding of the written description requirement one of ordinary skill in the art can distinguish the generic formula of the claims from other protein sequences and identify many species that the claims encompass.

On pages 28-31 of the Brief, appellants cite the Patent Office's Written Description Training Materials (http://www.uspto.gov/web/offces/pac/writtendesc.pdf). Example 14 of the Written Description Training Materials shows a full-length protein having SEQ ID NO: 3 and variants that are at least 95% identical to SEQ ID NO:3 and catalyze a reaction was concluded to meet the written description requirement of 35 U.S.C. § 112, 1st Paragraph. Appellants argue that the catalytic activity of Example 14 is analogous to the functional recitations in the appealed claims and that the protein variants of Example 14 is analogous to the clamed invention which contains an N-terminal amino acid sequence which is at least 70% homologous to SEQ ID NO: 1.

Appellants argue that pursuant to 37 CFR § 41.67(vii), ¶2, 2nd sentence, claim 65 should be considered separately with regard to the written description requirement since appellants allege that the specification exemplifies a wheat xylanase such that further recitation of SEQ ID NO: 1 and SEQ ID NO: 2 in claim 65 should not be required.

Appellants argue that pursuant to 37 CFR § 41.67(vii), ¶2, 2nd sentence, claims 66 and 67 should be considered separately with regard to the written description requirement since appellants allege that the specification exemplifies a wheat xylanase, as an example of a cereal xylanase inhibitor, such that further recitation of SEQ ID NO:

1 and SEQ ID NO: 2 in claims 66 and 67 should not be required. Appellants argue that appellants were in possession of a wheat, barley, and rye species which adequately describe the xylanase inhibitors of claims 66 and 67.

Appellants argue that pursuant to 37 CFR § 41.67(vii), ¶2, 2nd sentence, claim 68 should be considered separately with regard to the written description requirement since appellants argue that distinguishing characteristics (including water solubility, pI of greater than about 7.0, and molecular weight to about 40-43 kDa as measured by SDS-PAGE which resolves as tow separate bands of about 30 kDa and 10 kDa upon treatment with β-mercaptoethanol) are exemplified by the wheat, barley, and rye species of xylanase inhibitor and are deemed to be sufficient to meet the written description requirements of the *Eli Lilly* court.

Appellants' arguments have been fully considered but are not found to be persuasive. Guidelines for evaluation of patent claims for compliance with the written description requirement of 35 U.S.C. § 112 is found in MPEP 2163, section II. METHODOLOGY FOR DETERMINING ADEQUACY OF WRITTEN DESCRIPTION. Of particular relevance to appealed claims 48-50 and 52-56 is part (3) (C) (i) For Each Claim Drawn to a Single Embodiment Or Species (C) (2) which is reproduced below:

> (2) If the application as filed does not disclose the complete structure (or acts of a process) of the claimed invention as a whole, determine whether the specification discloses other relevant identifying characteristics sufficient to describe the claimed invention in such full, clear, concise, and exact terms that a skilled artisan would recognize applicant was in possession of the claimed invention. For example, if the art has established a strong correlation between structure and

> function, one skilled in the art would be able to predict with a reasonable degree of confidence the structure of the claimed invention from a recitation of its function. Thus, the written description requirement may be satisfied through disclosure of function and minimal structure when there is a well-established correlation between structure and function. **In contrast, without such a correlation, the capability to recognize or understand the structure from the mere recitation of function and minimal structure is highly unlikely. In this latter case, disclosure of function alone is little more than a wish for possession; it does not satisfy the written description requirement.** See *Eli Lilly*, 119 F.3d at 1568, 43 USPQ2d at 1406 (written description requirement not satisfied by merely providing "a result that one might achieve if one made that invention"); *In re Wilder*, 736 F.2d 1516, 1521, 222 USPQ 369, 372-73 (Fed. Cir. 1984) (affirming a rejection for lack of written description because the specification does "little more than outline goals appellants hope the claimed invention achieves and the problems the invention will hopefully ameliorate"). Compare *Fonar*, 107 F.3d at 1549, 41 USPQ2d at 1805 (disclosure of software function adequate in that art). (Emphasis added)

Claims 48-50 and 52-56 are genus claims drawn to a genus of any xylanase inhibitors which are water-soluble, alkaline proteins or glycoproteins that have a molecular weight of 40-43 kDa, pI of greater than about 7.0, and have the N-terminal amino acid sequence which is 70% homologous to SEQ ID NO: 1, where SEQ ID NO: 1 is a sequence of 14 amino acids. It is known in the art that the average molecular mass of an amino acid residue in a protein is about 0.11 kDa (See Proteins : Structures and Molecular Properties, 2nd ed.(1993), Thomas E. Creighton, p. 4, Table 1.1; reference made of record). Thus, the claimed genus encompasses proteins or glycoproteins that have amino acid sequences that contain approximately 333-358 amino acid residues since the claims recite a molecular weight of about 40-43 kDa. It should be noted that SEQ ID NO: 1 is a minimal amino acid sequence that accounts for only 14 out of approximately 333-358 amino acids residues contained within the claimed genus of proteins and glycoproteins since SEQ ID NO: 1 is only 14 amino acids in length.

The scope the genus includes many proteins or glycoproteins with widely differing structural, chemical, biological, and physical characteristics. Furthermore, the genus is highly variable because a significant number of structural differences between genus members exits.

The specification discloses a xylanase inhibitor which is a water-soluble, alkaline protein obtained from wheat having a molecular weight of 40-43 kDa, pI of greater than about 7.0, and consisting of two subunits with a partial N-terminal amino acid sequence of SEQ ID NO: 1 and SEQ ID NO: 2 (see specification p. 20, lines 1-16). The specification does not provide any sequence information for the disclosed rye and barley xylanase inhibitors. For the wheat xylanase inhibitor, the specification only provides minimal amino acid sequence information that identifies 31 amino acid residues out of approximately 333-358 amino acid residues of the wheat xylanase inhibitor, as evident by the 14 amino acids in SEQ ID NO: 1 and 17 amino acids in SEQ ID NO: 2. Since only 31 amino acids have been identified, then only 8.7%-9.3% of the entire amino acid sequence of the wheat xylanase inhibitor has been disclosed by the specification. The specification, however, does not describe any significant amino acid sequence and structure which is common to all members of the claimed genus. The specification does not disclose that the rye and barely xylanase inhibitors have both the minimal structures of SEQ ID NO:1 and SEQ ID NO: 2 of the wheat xylanase inhibitor. The specification does not describe a well-established correlation between the disclosed minimal structures of SEQ ID NO:1 and SEQ ID NO: 2 to any function. The

general knowledge and level of skill in the art do not supplement the omitted description because specific, not general, guidance is what is needed.

Since the specification fails to describe a well-established correlation between the disclosed minimal structure of SEQ ID NO:1 and SEQ ID NO: 2 to any function, and the specification fails to describe that the rye and barely xylanase inhibitors have the minimal structure of SEQ ID NO:1 and SEQ ID NO: 2, then one skilled in the art cannot predict, visualize, and recognize the identity of other members of the claimed genus of xylanase inhibitors.

Thus, as stated above, in view of MPEP 2163, section II. METHODOLOGY FOR DETERMINING ADEQUACY OF WRITTEN DESCRIPTION, part (3) (C) (i) For Each Claim Drawn to a Single Embodiment Or Species (C) (2):

> "...**without such a correlation, the capability to recognize or understand the structure from the mere recitation of function and minimal structure is highly unlikely. In this latter case, disclosure of function alone is little more than a wish for possession; it does not satisfy the written description requirement ."** (Emphasis added).

Although appellants cite that the post-filing date publication WO 01/98474 teaches a barely xylanase inhibitor HvXI has an has an N-terminal sequence of 20 amino acid residues that is 78.6% homologous to the N-terminal 14 amino acid residues (SEQ ID NO: 1) of the disclosed wheat xylanase inhibitor, the originally filed specification does not provide a description that would enable one skilled in the art to predict, visualize, and recognize that HvXI is a member of the claimed genus without actually isolating HvXI from barely, determining that HvXI is able to inhibit xylanase activity, and then elucidating the amino acid sequence of HvXI. Furthermore,

appellants have not described that HvXI of WO 01/98474 has the amino acid sequence of SEQ ID NO:2 of the wheat xylanase inhibitor disclosed by the specification. Thus, the skilled artisan cannot conclude that HvXI is a member species of the claimed genus since HvXI is not disclosed as having SEQ ID NO: 2 of the exemplified wheat xylanase inhibitor.

In regard to appellants' argument that Example 14 of the Patent Office's Written Description Training Materials (http://www.uspto.gov/web/offces/pac/writtendesc.pdf) is applicable to the claimed invention, it should be noted that in Example 14 the entire amino acid sequence of the protein was determined. This is not analogous to the claimed invention since only a minimal amount of sequence information is disclosed. As stated above, for the wheat xylanase inhibitor, the specification only provides minimal amino acid sequence information that identifies 31 amino acid residues out of approximately 333-358 amino acid residues of the wheat xylanase inhibitor, as evident by the 14 amino acids in SEQ ID NO: 1 and 17 amino acids in SEQ ID NO: 2. Since only 31 amino acids have been identified, then only 8.7%-9.3% of the entire amino acid sequence of the wheat xylanase inhibitor has been disclosed by the specification. Furthermore, the specification does not provide any sequence information for the disclosed rye and barley xylanase inhibitors. Thus, appellants' argument that Example 14 of the Patent Office's Written Description Training Materials is analogous to the claimed invention and that the written description requirement is satisfied is incorrect.

In view of the above considerations, one skilled in the art would not recognize that appellants were in possession of the claimed genus of any xylanase inhibitors

which are water-soluble, alkaline proteins or glycoproteins that have a molecular weight of 40-43 kDa, pI of greater than about 7.0, and have the N-terminal amino acid sequence which is 70% homologous to SEQ ID NO: 1, where SEQ ID NO: 1 is a sequence of 14 amino acids.

In regard to appellants' arguments that claims 65-68 should be considered separately with regard to the written description requirement and that further recitation of SEQ ID NO: 1 and SEQ ID NO: 2 should not required, of particular relevance is appellants' citation of 66 FR 1099, Friday, January 5, 2001 (attached to Brief as Evidence Appendix (e)) which states:

> "*Eli Lilly* explains that a chemical compound's name does not necessarily convey a written description of the named chemical compound, particularly when a genus of compounds is claimed. *Eli Lilly,* 119 F.3d at 1568, 43 USPQ2d at 1405. The name, if it does no more than distinguish the claimed genus from all others by function, does not satisfy the written description requirement because "it does not define any structural features commonly possessed by members of the genus that distinguish them from others. One skilled in the art therefore cannot, as one can do with a fully described genus, visualize or recognize the identity of the members of the genus." (see p. 1100, 1st column, lines 47-65)

Claims 65-68 are genus claims drawn to a genus of any xylanase inhibitors which are water-soluble, alkaline proteins or glycoproteins that have a molecular weight of 40-43 kDa, pI of greater than about 7.0, and resolve as two separate bands by SDS-PAGE analysis after reduction with β-mercaptoethanol, said two separate bands having molecular weights of about 30 kDa and 10kDa. It should be noted that the scope of

genus claims 65-68 is broader than the scope of genus claims 50-57 since genus claims 65-68 do not recite any structural properties such as a SEQ ID NO identifier of an amino acid sequence.

The scope of the genus includes many proteins or glycoproteins with widely differing structural, chemical, biological, and physical characteristics with no limitations on the composition of their amino acid sequences. Furthermore, the genus is highly variable because a significant number of structural differences between genus members exits.

As stated above, the specification discloses a xylanase inhibitor which is a water-soluble, alkaline protein obtained from wheat having a molecular weight of 40-43 kDa, pI of greater than about 7.0, and consisting of two subunits with a partial N-terminal amino acid sequence of SEQ ID NO: 1 and SEQ ID NO: 2 (see specification p. 20, lines 1-16). For this wheat xylanase inhibitor, the specification only provides minimal amino acid sequence information that identifies 31 amino acid residues out of approximately 333-358 amino acid residues of the wheat xylanase inhibitor, as evident by the 14 amino acids in SEQ ID NO: 1 and 17 amino acids in SEQ ID NO: 2. Since only 31 amino acids have been identified, then only 8.7%-9.3% of the entire amino acid sequence of the wheat xylanase inhibitor has been disclosed by the specification. Furthermore, the specification does not provide any sequence information for the disclosed rye and barley xylanase inhibitors.

To fully describe this claimed genus the specification must fully describe at least one species of the claimed genus sufficient to represent said genus whereby a skilled

artisan, in view of the prior art, could predict the structure of other species encompassed by the claimed genus. The specification, however, does not describe any significant amino acid sequence and structure which is common to all members of the claimed genus. The specification does not disclose that the rye and barely xylanase inhibitors have both the minimal structures of SEQ ID NO:1 and SEQ ID NO: 2 of the wheat xylanase inhibitor. The specification does not describe a well-established correlation between the disclosed minimal structures of SEQ ID NO:1 and SEQ ID NO: 2 to any function. The general knowledge and level of skill in the art do not supplement the omitted description because specific, not general, guidance is what is needed.

As stated above, appellants have not described that HvXI of WO 01/98474 has the amino acid sequence of SEQ ID NO:2 of the wheat xylanase inhibitor disclosed by the specification. Thus, the skilled artisan cannot conclude that HvXI is a member species of the claimed genus since HvXI is not disclosed as having SEQ ID NO: 2 of the exemplified wheat xylanase inhibitor.

In view of the above considerations, one skilled in the art would not recognize that appellants were in possession of the claimed genus of xylanase inhibitors which are water-soluble, alkaline proteins or glycoproteins that have a molecular weight of 40-43 kDa pI of greater than about 7.0, and resolve as two separate bands by SDS-PAGE analysis after reduction with β-mercaptoethanol, said two separate bands having molecular weights of about 30 kDa and 10kDa.

For the above reasons, it is believed that the written description rejection should be sustained.

Respectfully submitted,

Christian L. Fronda
Patent Examiner
Art Unit 1652

June 22, 2005

PONNATHAPU ACHUTAMURTHY
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

Conferees
Ponnathapura Achutamurthy
SPE Art Unit 1652

Michael Wityshyn
SPE Art Unit 1651

Michael G. Wityshyn (Conferee)
Supervisory Patent Examiner
Technology Center 1600

B.J. Sadoff
NIXON & VANDERHYE, PC
901 NORTH GLEBE ROAD, 11TH FLOOR
ARLINGTON, VA 22203